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Technical Memorandum for: State Weights and Measures Metrologists

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Subject: National Annual Assessment Summary – Quality Management System Topics (2014 to 2015 Submission)

Introduction

This memo provides a national overview and feedback for State weights and measures laboratories related to materials submitted for annual review by OWM as part of the Laboratory Recognition Program associated with NIST Handbook 143. During the 2014 to 2015 end-of-year review, special emphasis was placed on the reviewing the submitted recognition materials for compliance, as well as identifying trends and opportunities for improvement: quality management system (QMS) quality manuals, management review and quality audit reports.

Annual submissions are requested each year through an annual submission memorandum that is sent to all laboratories during the first two weeks of August. Each year, specific items are requested for review prior to issuing certificates of Recognition and special technical assessments are done of all materials in key areas. Laboratories are notified in advance what the special assessments will cover and training on those topics is generally provided to enable continual improvement and/or success in complying with Handbook 143 requirements. The published requirements in Handbook 143 include those of ISO/IEC 17025, as well as other OWM administrative and technical requirements. The annual submissions are submitted to OWM in the submission cycle between October 1 and November 1.

Special Guidance on Document Control (4.3). Quality management system documents are an important tool used within a state metrology laboratory to communicate policy and procedures to personnel who provide recognized measurements services to customers. One function of a healthy QMS that it that it's applied uniformly by all personnel. If some personnel are using different procedures, non-conforming work and corrective actions (and possibly recalls of work) may occur, which affects the quality of the work the customer will receive.

ISO/IEC 17025 notes that the term "document" can be broadly applied and includes "policy statements, drawings, plans, etc. . ." This broad definition essentially means that laboratories are faced with the task of managing large numbers of documents and spreadsheets that exist in many mediums, including hardcopy, electronic, digital, photographic, and written forms. Documents may come from both external and internal sources.

Document control is a process used to manage the lifecycle of a document, which includes five (5) phases: Creation, Review & Revision, Approval & Issue, Storage & Use, and Retirement. A robust document control process is fundamental in ensuring quality calibration services are received by laboratory customers.

Lab must set an appropriate review cycle or frequency for reviewing QMS documents. Typically this time period may be once per year (annually) or can be extended if changes are not likely required very often. Documents authored or written internally by the laboratory will likely require more frequent review than those created by external bodies (like national or international standards, specifications). Laboratories with large numbers of documents often develop a review schedule to spread their review work throughout the year, making it easier to fit into their busy calibration schedules.

Master List

A master list is a management system document that identifies the current revision status of all quality management system documents. The master list is required in ISO/IEC 17025 Section 4.3.2.1 to ensure that the current revision status and distribution of management system documents is established to prevent the use of INVALID or OBSOLETE documents. It's important to create a quality culture within an organization where the master list is always consulted before using a management system document to ensure that the correct approved version is being used. Using an out-of-date document is risky and can lead to nonconforming work, including generating customer calibration errors. Each master list entry typically includes the title, issuing authority (external or internal source), issue date (or version), and date for next scheduled review for each document.

The master list may be a stand-alone document or it may be included in a document control procedure. It is important to evaluate whether all master list documents are necessary and appropriate to the laboratory's current measurement scope and calibration activities. Why maintain procedures for calibrations that are not even performed? Removing unnecessary documents can make an instant impact and streamline document control efforts.

Obsolete or superseded documents may be needed for either legal or historical purposes. When these documents are removed from service and deleted from the master list, they must be suitably marked so laboratory personnel do not mistake them for active documents. Some laboratories have found it useful to designate a well-marked centralized storage location for their obsolete and historic documents to help ensure they are not unintentionally used. Authorized editions ("controlled copies") of QMS documents should be available at all locations where essential functions are performed.

External Documents

External documents are documents whose origin and control is by a body outside of your immediate organization. The lack of regular review of external documents is a common nonconformity. Regular review is necessary to determine if the latest version has been adopted. Examples might include documents:

- Necessary for the planning and operation of the QMS.
- Latest version of accepted international, regional, or national documentary standards, procedures, and specifications.
- Such as equipment manuals, charts, posters and other agency/organization laws, manuals, and directives.

Document Repository

It is convenient to store QMS documents in a centralized repository, such as a book shelf, file cabinet, or centralized electronic system (e.g., Share Point, internal webpage). Keeping track of the distribution (location) of documents will help track down and archive old copies that must be removed from service when they are replaced or become obsolete. The responsibility is on laboratory staff to check the version they plan to use against the version shown on the master list to ensure only the approved revision of a document is used.

National QMS Observations from Annual Submission Packages

During the upcoming 2016 review of submission materials, OWM will provide special attention and evaluation on the status and functionality of the QMS master list, management review process and records, and internal quality audit process and records. Reviewing the observations in this section and identifying gaps and opportunities for improvement will help ensure your laboratory QMS is operating efficiently, implementing recommended best practices, and providing quality traceable measurement services to customers.

In past reviews the following items have been observed for some laboratories as good practices:

- The Management Review included a written report, with executive summary, documented findings, and action plan with deadlines and evidence that actions have been evaluated for effectiveness. An excellent report balances brevity, relevant details, and completeness.
- Management Review meetings often used a PPT presentation (with photos and graphs) to efficiently communicate with top management and serve as supplemental objective evidence that should be maintained and submitted for recognition.
- An effective Management Review included a complete overview of all essential topic elements.
- QMS were often initially based on NISTIR 5802, a quality manual template that was developed according to the now obsolete ISO/IEC Guide 25:1990. These laboratories may identify master list components in multiple locations, including the Quality Manual Chapter 2 (References and Definitions), Appendix H (Procedures List), and Appendix N (Document Control). A best practice is to combine these reference sources into one location, the master list, which can serve as a centralized source of approved references.
- Quality manual chapters, appendices, and SAPs have been combined into one document for easy maintenance. Headers and footers are uniform throughout the QMS file. One version control identifier has been applied to the entire document even if individual sections were updated during the year and noted in the revision control section (e.g., Adopted April 2016).
- Internal quality audits were frequently documented using template forms, citing a variety of objective evidence, including laboratory records, administrative and technical process observations, and staff interviews. Action plans are being used to ensure that action items don't "slip through the cracks" and are completed according to established deadlines. Action item effectiveness is being monitored.

Opportunities for Improvement

- Laboratories that only write a Management Review report could enhance communication with top management by expanding written information into a PPT presentation with photos and graphs (data).
- A Management Review that is too short (i.e., only 2 to 3 pages). Some don't contain sufficient evidence that anything was discussed, an action plan and don't include evidence of monitoring action item effectiveness.
- Some laboratory quality manuals and associated documents have not updated since 2009! A five (5) year review cycle is inappropriate and will not support the goal of maintaining an efficient and functioning QMS.
- Only the quality manual updates were submitted, not a complete quality manual with appendices, SAPs, forms and other associated documents. OWM needs a complete set of all the materials that make up the QMS to examine and evaluate the current system as a whole during the recognition cycle.
- Quality manual document "track changes" should not be active in a QMS document that has been placed into service. All edits (i.e., underscores and ~~strikethrough~~) should be accepted or declined. The document should be clean and free of all edit markings.
- Quality manual, appendices, and SAPs are in separate document files and have individual dates on each individual document, some of which have no descriptive file name (just a section number) which must be independently maintained. Each document revision must be listed correctly on the master list table. Frequent nonconformities were observed between the actual file version (i.e., located in each separate electronic file footer) and the version found on the master list table.
- Confusing document control persists, especially the issue or revision dates. There may be one version date at the beginning of the document (i.e., 2007) which doesn't agree with the document headers (i.e., 10/28/2003) or with the table of contents (i.e., included changes up through 2013).
- The most important principle of file-naming is to be *consistent*. All documents will change or evolve over time (REVISION). Version changes are easily identified by a date used to represent the version: June 2016, 2016-06, or 2016-06-15.
- The QMS should have only one set of page numbers, preferably using the page X of Y format.
- The QM and each individual SAP electronic files have no Issuing Authority indicated in the file name (i.e., the laboratory name or abbreviation of the name).
- Combining the QM, SAPs, and appendices into one document is an opportunity for improvement. A recommended "first step" is to combine individual quality manual chapter files into one document, create uniform headers/footers, and use one version control throughout the document. Update the master list to reflect the change. The same can then be done to combine individual SAP files. Ultimately, the QM, SAPs, and appendices can be merged into one large document with consistent version control, headers, and footers.

- Many laboratory master lists weren't updated after the training provided at the 2014 C-RMAP. Reference citations should not use statements like "or later version if available."
- Some quality manual master lists were observed that did not include any revision or publication dates for listed documentary standards.
- The lack of regular review of Master List external documents was observed. Regular review is necessary to determine if a newer version is available and to ensure the latest version has been adopted.
- Reference documents have been observed to be listed in as many as five different locations within the QMS (providing opportunities for missing a section during review and for conflicting references in different sections).
- Quality audit template forms were used to document the process. However, objective evidence cells are frequently left completely blank. QM references, but not objective evidence noted.
- A note at the end of the audit report was often observed, stating that there is an "Objective Evidence" attachment. However, no objective evidence was found attached to the report or present in any of the other files. Attach objective evidence to the report (e.g., use a PDF and combine multiple files) or include the objective evidence files in the quality audit file folder.
- Some laboratories have only conducted a "desk audit" (i.e., evaluating presence of criteria) rather than a complete "functional audit" (i.e., observing laboratory operations to confirm compliance to criteria and QMS). These laboratories often only say "OK" in the objective evidence section without making any connection to the relevant quality system location or providing descriptions of the objective evidence (e.g., records, observations, staff interviews).
- Some internal audit reports are also missing an action plan. The report should include an executive summary, which provides a high level overview of the status of laboratory operations and summarizes the number and type of actions for top management. The audit report should include an action plan, as well as documented RCA, deadlines, and follow-up monitoring of actions for effectiveness.
- Some old audit findings (i.e., from prior audits, several years ago) were found present in the report. This may be the result of re-using prior audit reports. It's recommended to read the report in its entirety before finalizing the document to identify any discrepancies, including gaps, missing objective evidence or open (incomplete) action items.

Please consider these tips before submitting the next annual submission package:

- Don't send OWM a CONTROLLED COPY of the quality manual, appendices, Standard Administrative Procedures (SAPs and other related documents. Submit only UNCONTROLLED electronic copies.
- Review the entire Quality Management System (QMS) to determine if it still references "WMD" rather than "OWM." All references to NIST Weights and Measures Division (WMD) should be replaced with NIST Office of Weights and Measures (OWM).

- Double check to ensure that the management review and quality audit report document when the activity was initiated (e.g., a date or date range) and who conducted or participated in the activity.
- Review the quality of records and other objective evidence included in the submission package. Frequently, records supplied in the submission are scans of a hand written document and are illegible or of a poor resolution. At minimum we need to request a replacement scan before we can interpret the information. This will move your submission status to “Incomplete” and delay processing by OWM.
- Don’t evaluate the effectiveness on the same day the action item is completed. It’s necessary to give an action a little time to be used in normal operations before making an assessment to determine its effectiveness.